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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,237	09/27/2001	Jan Zavada	D-0021.5B-2	2855

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/967,237	**Applicant(s)** ZAVADA ET AL.	
	Examiner David J. Blanchard	**Art Unit** 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: *23*.
   Claim(s) rejected: *22,30,31,36-38,42,43 and 46-48*.
   Claim(s) withdrawn from consideration: *24-27,32-35,39-41,44,45 and 49-51*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

LARRY R. HELMS, PH.D
PRIMARY EXAMINER

Continuation of 3. NOTE: The amendments to claims 30 and 42 raise the issue of new matter. Presently amended claims 30 and 42 recite that the anti-idiotype antibody comprises an internal image corresponding to an epitope of said MN polypeptide, wherein the MN polypeptide is encoded by a polynucleotide at least 29 nucleotides in length (claim 30) and at least 25 nucleotides in length (claim 42). The disclsoure as filed does not provide adequate written support for anti-idiotype antibodies that bind to an antibody that binds to fragments of the MN polypeptide that are at least 8 amino acids in length and wherein the anti-idiotype antibody is an internal image of the MN polypeptide. The discsloure of specific monoclonal antibodies that bind to the MN protein and the identification of the epitopes that are recognized by these antibodies does not provide adequate wrtten support for the broader claimed subject matter, i.e., anti-idotypic antibodies that bind to any antibody that binds to just any fragment of the MN protein that is at least 8 amino acids in length.

Continuation of 5. Applicant's reply has overcome the following rejection(s): If, if, if entered, applicant's response would overcome the rejection of claims 22 and 46 under 35 U.S.C. 112, first paragraph, for lack of enablement. The rejection of claims 22-23, 30-31, 36-38 and 46-48 under 35 U.S.C. 103(a) as being unpatentable over Pastorekova et al as evidenced by Pastorek et al in view of Raychaudhuri et al.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's response does not overcome the rejections of claims 30, 36-38, 42-43 and 47-48 under 35 U.S.C. 112, first paragraph, lack of enablement and the rejection of claims 22, 30, 36-38, 42-43 and 46-48 under 35 U.S.C. 103(a) as being unpatentable over Oosterwijk et al [a] as evidenced by Uemure et al and Pastorek et al in view of Raychaudhuri et al and the rejection of claims 22, 30, 36-38, 42-43 and 46-48 under 35 U.S.C. 103(a) as being unpatentable over Oosterwijk et al [b] as evidenced by Uemure et al and Pastorek et al in view of Raychaudhuri et al.

With respect to the lack of enablement, applicant argues that claims 30 and 42 have been amended to indicate that the claimed anti-idiotype antibody "comprises an internal image corresponding to an epitope" of an MN protein or an MN polypeptide. The amendments to the claims has not provided any additional guidance or direction to assist the skilled artisan in practicing the claimed invention commensurate in scope with the claims. The specification does not provide adequate enablement for anti-iditypic antibodies that bind to the idiotype of an antibody that binds the myriad of MN polypeptide fragments as defined by the claims for reasons of record in the previous Office Action mailed 2/11/2005.

With respect to the rejection of claims 22, 30, 36-38, 42-43 and 46-48 udner 35 U.S.C. 103(a) as being unpatentable over Oosterwijk et al [a] as evidenced by Uemure et al and Pastorek et al in view of Raychaudhuri et al, applicant argues that the G250 antibody or hybridoma producing this antibody had not been deposited nor had the G250 protein or nucleic acid been characterized or identified as of the earliest effective filing date of the instant application, i.e., October 21, 1992. In response, applicant is reminded that the rejected claims are not drawn to any particular antibody, or even the G250 monoclonal antibody. Further, applicant has not provided any evidence or arguments why one of ordinary skill in the art following the teachings of Oosterwijk [a] and using renal cell carcinomas as a source of antigen would not produce antibodies that recognize the MN protein expressed by renal cell carcinomas.

With respect to the rejection of claims 22, 30, 36-38, 42-43 and 46-48 udner 35 U.S.C. 103(a) as being unpatentable over Oosterwijk et al [b] as evidenced by Uemure et al and Pastorek et al in view of Raychaudhuri et al, applicant argues that the G250 antibody or hybridoma producing this antibody and not been deposited and one of skill in the art would not have been able to produce the G250 monoclonal antibody reproducibly. Further, applicant argues that the G250 protein or nucleic acid been characterized or identified as of the earliest effective filing date of the instant application, i.e., October 21, 1992. In response, applicant is reminded that the rejected claims are not drawn to any particular antibody, or even the G250 monoclonal antibody. Further, applicant has not provided any evidence or arguments why one of ordinary skill in the art following the teachings of Oosterwijk [b] and using renal cell carcinomas as a source of antigen would not produce antibodies that recognize the MN protein expressed by renal cell carcinomas.

LARRY R. HELMS, PH.D
PRIMARY EXAMINER